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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,835	07/15/2003	John P. Cooke	080618-0237	4352

22428 7590 09/22/2004

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,835	COOKE ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *34 pages*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The status of the parent applications recited in the claim for priority inserted at page 1 of the specification needs to be updated.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 33-37, 40-44, 56-59, 62, 65-70, 82-85, 87-94, 96-100, and 103-107 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the limitation "wherein the at least one arginine compound is not a precursor of nitric oxide", as is recited in instant claims 23, 33, 40, 62, 65, 88, and 96. The original disclosure makes clear that the arginine compound is a precursor of nitric oxide. See, e.g., page 11, lines 16-17. There is no original disclosure supporting the limitation that "the at least one arginine compound represents the greatest percentage by weight when compared to the percentage weight of each other active ingredient in the composition" (see claims 34, 41, 56, 67, 82, 87, 98, and 104) or that "the at least one arginine compound is the predominant active ingredient in the composition" (see claims 66 and 97) or that "the at least one arginine compound represents the greatest percentage by weight in the dietary supplement" (see claim 89). There is no literal support in the original disclosure for these limitations, and the possibility that these relationships may hold true for a few specific examples in the specification does not provide support for the broader concentration ranges recited in these claims. There is no original

disclosure supporting the limitation that the composition or dietary supplement comprises at least about 75 mol % of the at least one arginine compound, as is recited in instant claims 37, 44, 59, 70, 85, 92, 100, and 107. There is no literal support in the original disclosure for the claim limitation. The specification at page 12, lines 2-5, discloses oligopeptides in which at least about 75% of the amino acid residues are arginine or lysine; however, this section is not discussing arginine proportions in relationship to the composition or dietary supplement as a whole. There is no original disclosure supporting the limitation that "the at least one arginine compound represents at least about 2.25% by weight of the active ingredients" as is recited in claim 93. There is no literal support in the original disclosure for the claim limitation. While pages 18 and 22 of the specification disclose examples in which 2.25% by weight of arginine is added to water and fed to rats, there are no other active ingredients in these examples, and the arginine represents 100% by weight of the active ingredients. Applicants have not indicated where the original disclosure of the invention supports the new claim limitations.

3. Claims 23, 33, 40, 62, 65, 88, and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meaning of the limitation in claims 23, 33, 40, 62, 65, 88, and 96 that "the at least one arginine compound is not a precursor of nitric oxide" is unclear because Applicants' specification makes it clear that the arginine compound is and is intended to be a precursor of nitric oxide. See, e.g., page 11, lines 16-17, of the specification.

4. Claims 95-10 are objected to because of the following informalities: At claim 95, line 3, "select" should be changed to "selected". Appropriate correction is required.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 87-93 and 101-107 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,428,070. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '070 patent. Note that the only active ingredient present in the claimed method of the '070 patent is an arginine compound.

7. Claims 32-38, 61-63, 87-94, and 101-107 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,945,452. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '452 patent anticipate instant claims 87-94 and 101-107. Note that the only active ingredient present in the claimed method of the '452 patent is an arginine compound. With respect to instant claims 32-38 and 61-63, although the '452 patent does not claim its dietary supplement in the form of a pill, powder, liquid, or capsule, it would have been obvious to one of ordinary skill in the art to administer the dietary supplements recited in the claimed compositions of the '452 patent in the form of a pill, powder, liquid, or capsule because the '452 patent claims oral administration, and pills, powders, liquids, because capsules are well-known and commonly-used forms for the administration of dietetic, nutritional, and

pharmaceutical agents; and because the form of the dietary supplements to be administered in the claimed method of the '452 patent would not have been expected to affect the in vivo activities of the active agents.

8. Claims 22-28, 30-44, 47-51, 53, 54, 61-70, 73-77, 79, 80, and 87-107 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,891,459. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '459 patent anticipate instant claims 22-26, 28, 30-33, 38-40, 47-49, 51, 53, 54, 61-65, 73-75, 77, 79, 80, 95, 96, 101, and 102. With respect to instant claims 27, 50, and 76, although the '459 patent does not claim its dietary supplement in the form of a pill, it would have been obvious to one of ordinary skill in the art to administer the dietary supplements recited in the claimed compositions of the '459 patent in the form of a pill because the '459 patent claims oral administration, and pills are well-known and commonly-used forms for the administration of dietetic, nutritional, and pharmaceutical agents; and because the form of the dietary supplements to be administered in the claimed method of the '459 patent would not have been expected to affect the in vivo activities of the active agents. Note that glutathione is a sulfhydryl-containing antioxidant. With respect to instant claims 34-37, 41-44, 66-70, 87-94, 97-100, and 103-107, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal proportions for the active agents in the dietary supplements in the claimed invention of the '459 patent because component proportion is an art-recognized result-effective variable which is routinely determined and optimized in the dietary and pharmaceutical arts.

9. Claims 32-38, 61-63, and 101 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,117,872. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '872 patent anticipate instant claims 32, 38, 61, 63, and 101. Note that the '872 patent, especially in claims 7-9, claims administering arginine in combination with an agent which enhances ENDO synthesis (which corresponds to Applicants' at least one additional compound associated with production of nitric oxide other than the at least one arginine compound), and claims administration in the form of a shake (which corresponds to Applicants' liquid). With respect to instant claims 33 and 62, it would have been obvious to one of ordinary skill in the art to administer a claimed composition according to the '872 patent in which arginine is the only amino acid present because the claims of the '872 patent permit choosing one of the two recited amino acids while still achieving the claimed results, and because choice of only amino acid would reduce the number of measuring and mixing steps necessary to produce the composition administered in the claimed method of the '872 patent. With respect to instant claims 34-37, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal proportions for the active agents in the dietary supplements in the claimed invention of the '872 patent because component proportion is an art-recognized result-effective variable which is routinely determined and optimized in the dietary and pharmaceutical arts.

10. Claims 22-107 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,646,006. Although the conflicting claims are not identical, they are not patentably distinct from each other because

the claims of the '006 patent anticipate instant claims 22-33, 38-40, 45-55, 60-65, 71-81, 86, 95, 96, and 104. With respect to instant claims 34-37, 41-44, 56-59, 66-70, 82-85, 87-94, 97-100, and 102-107, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal proportions for the active agents in the dietary supplements in the claimed invention of the '006 patent because component proportion is an art-recognized result-effective variable which is routinely determined and optimized in the dietary and pharmaceutical arts.

11. Instant claims 23, 33-37, 40-46, 56-59, 62, 65-72, 82-85, 87-94, 96-100, and 103-107 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 08/336,159 because the parent application '159, under the test of 35 U.S.C. 112, first paragraph, does not disclose an arginine compound which is not a precursor of nitric oxide; does not disclose compositions in which the arginine compound is the greatest percentage by weight compared to the other active ingredients, is at least about 10% or at least about 25% by weight of the active ingredients, is present in amounts of at least about 75 mol %, is the predominant active ingredient, or is present in an amount of at least 2.25% by weight of the active ingredients; and does not disclose co-administration of a partially oxidized nitrogen compound such as a nitroso compound.

Instant claims 55, 60, 81, and 86 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 08/076,312 because the parent application '312, under the test of 35 U.S.C. 112, first paragraph, does not disclose co-administration of a grape skin extract.

Instant claims 22, 24-32, 38, 39, 47-54, 61, 63, 64, 73-80, 95, 101, and 102 are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 08/076,312

because the parent application '312, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed subject matter.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

13. Claims 87-93 and 103-107 are rejected under 35 U.S.C. 102(b) and claims 101 and 102 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Barbul (U.S. Patent No. 5,157,022). Barbul teaches orally administering 30 g per day of arginine salts to humans. See, e.g., Example 1. No other ingredient is described as being present with the arginine salts, and therefore Barbul's arginine meets Applicants' claimed arginine concentrations. Because the same active agent is being administered to the same humans according to the same method steps, inherently endothelial nitric oxide will be enhanced in Barbul to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of Barbul and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed method is unobviously different than that of Barbul.

14. Claims 22, 26, 30-32, 39, 53, 54, 61, 64, 79, 80, 95, and 101 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent Application 259,167. The European Patent Application '167 teaches an orally ingestible aqueous solution comprising arginine; lysine, vitamin B6, folic acid, vitamin B12, and calcium (which correspond to Applicants' at least one additional compound associated with production of nitric oxide other than the at least one arginine compound - see page 12, line 31 - page 31, line 1); and cysteine, vitamin C, and vitamin E (which correspond to Applicants' at least one antioxidant or at least one compound that prevents the production of oxygen-derived free radicals - see page 13, lines 1-7). See, e.g.,

Examples 1-4. In view of the similarity in composition and method steps between the European Patent Application '167 and the instant claimed invention, inherently the aqueous solution of the European Patent Application '167 will enhance nitric oxide production and will enhance endothelial nitric oxide to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the composition and method of the European Patent Application '167 and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed method and composition is unobviously different than that of the European Patent Application '167.

15. Claims 24, 25, 34-38, 41-44, 47-49, 63, 66-70, 73-75, 97-100, and 102-107 are rejected under 35 U.S.C. 103(a) as being obvious over the European Patent Application 259,167. Application of the European Patent Application '167 is the same as in the above rejection of claims 22, 26, 30-32, 39, 53, 54, 61, 64, 79, 80, 95, and 101. The European Patent Application '167 does not teach Applicants' claimed amounts, percentages, and proportions. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal amounts, percentages, and proportions for the compositions of the European Patent Application '167 because amounts, percentages, and proportions are art-recognized result-effective variables which are routinely determined and optimized in the nutritional arts.

16. Claims 22, 24-26, 30, 32, 38, 39, 47-49, 53, 61, 63, 64, 73-75, 79, 95, 101, and 102 are rejected under 35 U.S.C. 102(a) and claims 23, 33-37, 40-44, 62, 65-70, 87-94, 96-100, and 103-107 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent Application 511,587 in view of Roy (U.S. Patent No. 5,348,755). The European Patent Application '587

teaches an edible aqueous solution comprising arginine as the only amino acid and also comprising vitamin B6 (which corresponds to Applicants' at least one additional compound associated with production of nitric oxide other than the at least one arginine compound - see page 12, line 31 - page 31, line 1) and citric acid (which corresponds to Applicants' at least one antioxidant or at least one compound that prevents the production of oxygen-derived free radicals - see page 13, lines 1-7). See, e.g., Table 1, formulations 1 and 2. Roy teaches that citric acid is a known anti-oxidant. See, e.g., column 3, lines 46-48; column 11, lines 34-41; and claim 7. In view of the similarity in composition and method steps between the European Patent Application '587 and the instant claimed invention, inherently the aqueous solution of the European Patent Application '587 will enhance nitric oxide production and will enhance endothelial nitric oxide to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the composition and method of the European Patent Application '587 and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed method and composition is unobviously different than that of the European Patent Application '587.

17. Claims 22, 24-26, 30, 32, 38, 39, 47-49, 53, 61, 63, 64, 73-75, 79, 95, 101, and 102 are rejected under 35 U.S.C. 102(a) and claims 23, 33-37, 40-44, 62, 65-70, 87-94, 96-100, and 103-107 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent Application 511,587 as applied against claims 22-26, 30, 32-44, 47-49, 53, 61-70, 73-75, 79, and 87-107 above, and further in view of Levere et al (U.S. Patent No. 5,217,997) or the Castillo et al article (PNAS, Vol. 90, pages 193-197; Reference C46 of the Information Disclosure Statement filed May 21, 2004). The European Patent Application '587 does not disclose that oral administration

of arginine enhances the level of endogenous NO in the vascular system. Levere et al teach that L-arginine is converted to nitric oxide by endothelial cells and in arteries (see, e.g., column 3, lines 11-37, and column 7, lines 21-32), and the Castillo et al article teach that dietary arginine is converted into nitric oxide in the planchnic region (see, e.g., the Abstract), and thus are further evidence that the process and composition disclosed by the European Patent Application '587 anticipate Applicants' claimed processes and compositions and achieve Applicants' claimed effects on endothelial and endogenous nitric oxide levels.

18. Claims 27, 28, 50, 51, 76, and 77 are rejected under 35 U.S.C. 103(a) as being obvious over the European Patent Application 511,587 in view of Levere et al (U.S. Patent No. 5,217,997) or the Castillo et al article (PNAS, Vol. 90, pages 193-197; Reference C46 of the Information Disclosure Statement filed May 21, 2004). Application of the European Patent Application '587, Levere et al, and the Castillo et al article is the same as in the above rejection of claims 22-26, 30, 32-44, 47-49, 53, 61-70, 73-75, 79, and 87-107. The European Patent Application '587 does not teach its arginine-containing compositions in pill form, and does not specifically exemplify the use of arginine in the form of a hydrochloride salt. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to formulate and administer the arginine-containing compositions of the European Patent Application '587 in the form of a pill, because the European Patent Application '587 permits the arginine-containing compositions to be formulated and administered in a wide variety of physical forms (see, e.g., page 3, line 53 - page 4, line 11), because pills are widely known and have the benefit of ease of storage, transportation, measurement, and administration, and because the physical form of the arginine would not have been expected to affect materially the arginine's

ability to be administered and converted to nitric oxide as taught by Levere et al and the Castillo et al article. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use arginine hydrochloride as the source of arginine in the arginine-containing compositions of the European Patent Application '587 because the European Patent Application '587 teaches arginine hydrochloride to be a useful source of arginine for its arginine-containing compositions (see, e.g., page 3, lines 7-9) and because the particular salt form of the arginine would not have been expected to affect materially the arginine's ability to be administered and converted to nitric oxide as taught by Levere et al and the Castillo et al article.

19. Claims 33-37, 62, 87-94, and 103-107 are rejected under 35 U.S.C. 102(a) as being anticipated by the South African Patent 9410015. The South African patent teaches a composition comprising L-arginine, Vitamin D3, and calcium. The composition is administered orally in the form of a capsule comprising about .4 grams of arginine, with a daily dosage of two capsules. See, e.g., page 3, lines 2-9, and the paragraph bridging pages 5 and 6. Because the process steps, active agents, and patients are the same in the South African patent as in Applicants' claimed invention, inherently nitric oxide production will be enhanced in the South African patent to the same extent claimed by Applicants.

20. Claims 87-107 are rejected under 35 U.S.C. 102(e) as being anticipated by Greenberg et al (U.S. Patent No. 5,780,039). Greenberg et al teach the oral administration of nutrition compositions comprising arginine. Specifically exemplified is a nutrition bar comprising 4 grams of L-arginine phosphate and also comprising folic acid, B_{12}, B_6, and calcium (which correspond to Applicants' at least one additional compound associated with production of nitric oxide other than the at least one arginine compound - see page 12, line 31 - page 31, line 1), and

Vitamin C, Vitamin E (i.e., tocopherol), and β-carotene (which correspond to Applicants' at least one antioxidant or at least one compound that prevents the production of oxygen-derived free radicals - see page 13, lines 1-7). No other amino acids are present in the nutrition bar. Greenberg et al also teach their compositions in the form of a dry powder. See, e.g., column 5, lines 36-43; column 7, lines 3-29; Example IV; and the claims. Because the process steps, active agents, and patients are the same in Greenberg et al as in Applicants' claimed invention, inherently endothelial nitric oxide will be enhanced in Greenberg et al to the same extent claimed by Applicants.

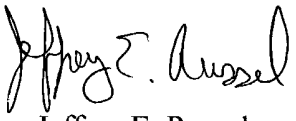
21. Claims 87-107 are rejected under 35 U.S.C. 102(e) as being anticipated by Greenberg et al (U.S. Patent No. 5,780,039) as applied against claims 87-107 above, and further in view of Levere et al (U.S. Patent No. 5,217,997) or the Castillo et al article (PNAS, Vol. 90, pages 193-197; Reference C46 of the Information Disclosure Statement filed May 21, 2004). Greenberg et al do not disclose that oral administration of arginine enhances the level of endogenous NO in the vascular system. Levere et al teach that L-arginine is converted to nitric oxide by endothelial cells and in arteries (see, e.g., column 3, lines 11-37, and column 7, lines 21-32), and the Castillo et al article teach that dietary arginine is converted into nitric oxide in the planchnic region (see, e.g., the Abstract), and thus are further evidence that the process and composition disclosed by Greenberg et al anticipate Applicants' claimed processes and compositions and achieve Applicants' claimed effects on endothelial and endogenous nitric oxide levels.

22. Reference A62 of the Information Disclosure Statement By Applicant filed April 19, 2004 has not been considered by the examiner because it is not in the English language, and because no concise explanation of its relevance has been provided. See 37 CFR 1.98(a)(3)(i).

The citation for Reference A104 in the same Disclosure Statement has been corrected to match the reference that was actually provided during prosecution of parent application 10/060,252.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

September 8, 2004

BRUCE KISLIUK, DIRECTOR
TECHNOLOGY CENTER 1600